REMARKS

The Office Action dated September 17, 2009 has been reviewed and the comments of the U.S. Patent and Trademark Office have been considered. The following remarks are respectfully submitted to place the application in condition for allowance.

1. Summary of Claims

A detailed listing of all claims that are, or were, in the application, irrespective of whether a claim remains under examination in the application, is presented, with an appropriate defined status identifier. Claim 5 is pending, and claims 1-4 and 6-10 were cancelled previously.

Applicants have amended claim 5, and added claim 11. Support for claim 11 and the amendment to claim 5, can be found in the disclosure, *inter alia*, at page 6, ll. 6-21. No new matter has been added by the claim amendments. Applicants respectfully request entry of the amended claims.

2. Claim Rejection under 35 USC § 103

The Office rejected claim 5 under 35 USC § 103(a) as allegedly being obvious over Stein *et al.*, (*Journal of Medical Virology*, 1994)("Stein"), in view of Servais *et al.*, (*GenBank Accession No. CAB86592*, 2001) ("Servais") and Kim *et al.*, (*Aids Research and Human Retroviruses*, 2001)("Kim").

The Office asserted that Stein discloses a HIV reverse transcriptase with a mutation at position 194 from wild type amino acid glutamate, and correlating the presence of the mutation to a change in effectiveness or susceptibility of the nucleoside reverse transcriptase inhibitor azidothymidine (AZT). Office Action at page 4. The Office then cited Servais as disclosing the E194G mutation in the reverse transcriptase in samples from patients who had been treated with the reverse transcription inhibitors (RTIs) zidovudine and zalcitabine. *Id.* The Office acknowledged that Stein and Servais do not teach introducing a RTI for a second therapy to a previously treated patient sample containing the E194G mutation, and cited Kim as allegedly disclosing introducing HIV nucleoside enzyme transcriptase inhibitor 3'-fluoro-3'-deoxythymidine (FLT) to both a wild-type HIV-1 isolate and multidrug-resistant HIV-1 isolates. *Id.*

Applicants have amended claim 5 to clarify a method for evaluating a change in susceptibility of HIV to a reverse transcriptase inhibitor for a second anti-HIV therapy comprising:

(i) receiving a sample from an HIV-infected patient who has been treated with a first anti-HIV therapy;

(ii) determining whether said sample from said HIV-infected patient comprises an HIV reverse transcriptase having a mutation at the position 194, wherein the wild type amino acid glutamate is mutated to glycine (E194G) as compared to the wild-type HIV strain IIIB/LAI; (iii) introducing a reverse transcriptase inhibitor selected from Nevirapine, Efavirenz, Abacavir, Capravirine, Lamivudine, Didanosine, Stavudine, Adefovir, Delavirdine, DPC-086, DPC-083, Tenofovir, and compound 1 (Benzonitrile, 4-[[6-amino-5-bromo-2-[(4-cyanophenyl)-amino]-4-pyrimidiny-l]oxy]-3,5-dimethyl-, compound 1) for said second anti-HIV therapy to said sample from said HIV-infected patient containing said mutation. Stein, Servais and Kim do not teach introducing a reverse transcriptase inhibitor selected from Nevirapine, Efavirenz, Abacavir, Capravirine, Lamivudine, Didanosine, Stavudine, Adefovir, Delavirdine, DPC-086, DPC-083, Tenofovir, and compound 1 (Benzonitrile, 4-[[6-amino-5-bromo-2-[(4-cyanophenyl)-amino]-4-pyrimidiny-l]oxy]-3,5-dimethyl-, compound 1) for said second anti-HIV therapy.

In addition, Applicants have added claim 11 directed to the method of claim 5 further comprising: (vii) determining whether said sample from said HIV-infected patient comprises an HIV reverse transcriptase having a mutation E194G compared to the wild-type HIV strain IIIB/LAI, and at least one additional mutation in the HIV reverse transcriptase of the wild-type HIV strain IIIB/LAI at the position selected from 41, 62, 65, 67, 69, 70, 74, 75, 98, 100, 101, 103, 106, 108, 116, 118, 138, 151, 178, 181, 184, 188, 190, 210, 215, 219, 225, 227, 230, 234, 236, and 238; (viii) determining the susceptibility of said HIV having said reverse transcriptase mutations of step (vii) to said HIV reverse transcriptase inhibitor in said sample; (ix) comparing the anti-HIV drug effectiveness in said sample containing said reverse transcriptase mutations with a sample not containing such said mutations; and (x) correlating the presence of said reverse transcriptase mutations of step (vii) to a change in the susceptibility of said HIV reverse transcriptase inhibitor.

In light of the claim amendments and comments above that Stein in view of Servais and Kim do not teach all of the elements of the claimed invention, one of skill in the art would have

no reason to combine the references to perform the claimed method for evaluating a change in susceptibility of HIV to a reverse transcriptase inhibitor. The skilled artisan would have no reasonable expectation of success to perform the method that uses the HIV reverse transcriptase inhibitors selected from the defined group. Thus, Applicants respectfully request withdrawal of the rejection of claim 5 under 35 U.S.C. § 103(a)

3. Conclusion

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Applicants submit concurrently a request for a two-month extension of time under 37 C.F.R. § 1.136 and the accompanying fee of $490.00 set forth in 37 C.F.R. § 1.17(a)(2) paid by Credit Card. In the event that any additional extensions of time are necessary to prevent the abandonment of this patent application, then such extensions of time are petitioned. The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction with this submission to Deposit Account Number 50-2228, under Order No. 026038.0248PTUS, from which the undersigned is authorized to draw.

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Respectfully submitted,

By _____

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